REMARKS

Applicants respectfully request reconsideration of this application, and reconsideration of the Office Action dated September 9, 2003 (Paper No. 18). Upon entry of this Amendment, claims 1-20 will remain pending in this application. The amendments to the claims are supported by the specification and original claims. No new matter is incorporated by this Amendment.

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Claims 5-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The Office Action maintains that claim 5 is indefinite because it is purportedly unclear what is intended by the terms "skins structures", "micronutrients of the skin", "sensorial agents."

Applicants again respectfully submit that those of ordinary skill in the art would readily understand the metes and bounds of claim 5. Applicants enclose herewith printed pages from some Internet sites which show that the expressions "skin structure" and "micronutrients of the skin" are conventionally used in the cosmetic area.

As for the terminology "sensorial agents", Applicants have amended claim 5 to instead recite "sensory agents." The terminology "sensory agents" represents a more accurate English translation for the Portuguese terms "agentes sensoriais" which were used in the priority document. Moreover, Applicants also enclose herewith an Internet site which defines the term "sensory" as far as the cosmetic industry is concerned. Fragrance is cited there just as an illustrative example.

With respect to rejections under 35 U.S.C. § 112, second paragraph, the M.P.E.P teaches:

> **The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:**
>
> **(A) The content of the particular application disclosure;**

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. M.P.E.P. § 2173.02

As has been previously asserted, the specification gives examples of "skins structures", "micronutrients of the skin", and "sensory agents." Moreover, Applicants have provided evidence which shows how those possessing ordinary skill in the art would interpret these terms. Accordingly, as evidenced by the above, those of ordinary skill in the art to which the claimed invention most closely relates would readily understand what is intended by these terms. Hence, Applicants again respectfully request that this rejection be withdrawn.

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Claims 1-20 are rejected under 35 U.S.C. § 103(a) as purportedly obvious based on Rinaldi et al. (U.S. Pat. No. 5,891,470) in view of Huc et al. (U.S. pat. No. 5,395,620). Applicants respectfully traverse this rejection.

Rinaldi, describes a "softgel" containing retinol and ascorbic acid impregnated on porous microparticles. The softgel is a single-use product. In other words, Rinaldi's product contains a single dosage. Once Rinaldi's product has been opened and used, it is to be discarded. For an additional application, a fresh Softgel is needed since it contains from 0.1 to 2.0 mL of filling material. See Column 1, Lines 28-34. However, the Softgel composition is incompatible with water since water dissolves the Softgel walls. See Column 1, Lines 40-43.

According to a first embodiment of Rinaldi's invention (column 7, line 45 to column 4, line 5), it is necessary to protect the retinol in order to avoid its degradation due to the presence of light, oxygen and heating (column 4, lines 30-35) and that is why ascorbic acid is added, as it is known to be a strong antioxidant. Ascorbic acid is used in the solid form which prevents it from ionization (ionization being the chemical condition when LAA degradation begins). Apart from that, the process for producing the Softgel disclosed in Rinaldi is complex and expensive. See column 4, lines 35-41.

In a second formulation taught by Rinaldi (column 8, lines 5-28), a Softgel is prepared with ascorbic acid. Again the ascorbic acid comprised in the microparticles is in the solid state, since it is susceptible to degradation in the presence of water and still more susceptible to degradation when the ascorbate ion is in the presence of oxygen and metallic ions.

Upon checking the examples presented in Rinaldi, it is clear that that formulations of Examples 1 to 3 are free from water (column 8, line 30 to column 9, line 30). This is evident since the microparticles mentioned by those inventors (and known as Microsponges ® of Advanced Polymer Systems (column 3, lines 39-41)) contain ascorbic acid (0.023%) that will only be released in the presence of water upon use. Therefore, while the product is closed, the ascorbic acid will be kept stable. Only when the user applies the cosmetic product over the skin will the ascorbic acid be in contact with water and released on the skin surface by a diffusion phenomenon known to those skilled in the art. This is because the microparticles (Microsponges ®) described by Rinaldi do not penetrate the skin.

The invention claimed in the present patent application actually refers to the synergy between the ascorbic acid and retinol in the cellular activity. This effect is shown in the Figures and described in the instant specification. This effect was surprisingly detected by the present inventors since there was no indication of such technical result in the literature.

In the present invention, microcapsules, which are made of biologically active material (an example of such micropoarticles being Talaspheres ®), are used in order to protect retinol and ascorbic acid and make it possible to prepare stable cosmetic compositions. Applicants' microparticles make preparation and packing much easier, without the need of complex and expensive processes. In addition, because of the use of the microparticles, the water content of Applicants' formulation can be over 40%, which would normally be an appropriate medium for the degradation of ascorbic acid. However, degradation does not happen due to the presence of the microcapsules which act as a barrier for the contact of LAA with water.

Applicants invention includes a first group of microparticles containing retinol and a second group of microparticles containing ascorbic acid. This second group, having a composition different from the first group, are contacted with the skin, penetrate the skin, and only release the contents thereof due to enzymatic reactions. Thus, retinol and ascorbic acid are released in a region very close to the target cells. Consequently, the retinol and ascorbic acid are not exposed to conditions that can lead to degradation (such as light, oxygen and water when on the skin and water and free radicals when in the inner layers of the skin).

Rinaldi does not show nor foresee the actual way of action disclosed in the present application nor the way the microcapsules are indeed used. In other words, as conceded in the Office Action, the microparticles employed by Rinaldi are not the same as the microparticles used in the present invention. In fact, the microparticles used by Rinaldi have very different properties from those used in the present invention.

Applicants now turn to Huc which teaches the preparation of microcapsules made of biologically active material. However, Huc neither teaches nor fairly suggest putting Vitamin A and an antioxidant into a first group of microspheres, and Vitamin C into a second group of microspheres. Moreover, Huc does not mention nor suggest the possibility of a synergistic effect between the ascorbic acid and retinol in the enhancement of cellular activity.

In view of the above, Applicants submit that those of ordinary skill in the art could come up with the present invention only after reading the present application. Thus, Applicants submit the rejection is improperly based on hindsight. This is because, as explained above, the teachings of these two cited patents would not have been sufficient to lead one of ordinary skill in the art to the present invention.

Recent case law has stressed the requirement that to establish a *prima facie* case of obviousness, the Examiner must provide factual support from the cited patents for the proposed modification. This factual support must be based on objective evidence of record and must establish that the cited patents themselves provide the requisite motivation, suggestion, or teaching

regarding the desirability of making the specific combination made by the Appellant. The factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. It is improper to determine whether a person of ordinary skill would have been led to this combination of references based upon hindsight. In re Sang Su Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

Applicants make the following additional comments with respect to independent claims 19 and 20. Claim 19 states that the Vitamin C is present in an amount effective for enhancing the action of the Vitamin A on the cellular activity of an individual. Claim 20 states that the Vitamin C is present at a concentration of about 0.02% by weight, and the Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition. Neither of these two features are taught or fairly suggested by Rinaldi or Huc. Moreover, contrary the assertion in the Office Action, the specification and Figures provide ample evidence showing the synergistic effect that occurs as a result of the claimed invention.

As stated in the previous Amendment, Rinaldi uses vitamin concentrations which are much higher than the present invention. The advantage provided by Applicant's invention with respect to using lower vitamin concentrations is explained by the releasing mechanism of the microcapsules claimed in Rinaldi. According to the teachings of Rinaldi, the vitamins are released on the skin surface and permeate the skin to reach the target sites. Upon permeating the skin, the vitamins (which are natural antioxidants) may be inactivated. Therefore, the actual vitamin concentration acting on the target sites is much lower than the concentration initially present in the formulation. Thus, an initial higher concentration must be used in the product disclosed by Rinaldi. Moreover, Rinaldi fails to teach including Vitamin C in an amount effective for enhancing the action of the Vitamin A on the cellular activity of an individual as recited in claim 19 or the recited concentrations of claim 20.

The amendments to claims and above Remarks overcome this objection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

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Applicants respectfully submit that this Amendment and the above remarks obviate the outstanding rejections in this case, thereby placing the application in condition for immediate allowance. Allowance of this application is earnestly solicited.

If any fees under 37 C.F.R. §§ 1.16 or 1.17 are due in connection with this filing, please charge the fees to Deposit Account No. 02-4300; Order No. 032286.006.

If an extension of time under 37 C.F.R. § 1.136 is necessary that is not accounted for in the papers filed herewith, such an extension is requested. The extension fee should be charged to Deposit Account No. 02-4300; Order No. 032286.006.

Respectfully submitted,
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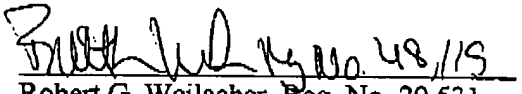
By:  Reg. No. 48,119

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RGW/BLN

1) Skin structures –

http://www.antiaging-systems.com/extract/skinaging.htm

http://www.helenshaven.com/about.htm

The article presented in this site reads:

The Importance of Collagen and Elastin

Collagen, composed of amino acids, is a protein forming the structural grid that holds other skin structures together in the dermis. It gives the skin its strength and durability. It is primarily composed of a few specific amino acids, proline, hydroxyproline, lysine and glycine. Some experts believe that foods or supplements rich in these amino acids may benefit the skin by stimulating collagen production. There is a number of topical ways to stimulate collagen production, including topical vitamin C and copper peptides. Increasing collagen production is important because age-related decline in the collagen synthesis is partly responsible for the signs of skin aging such as thinning, wrinkles and sagging.

http://www.aarogya.com/familyhealthlifestyle/teens/skin/index.asp

Under the title "nutrition" this article reads:

> All structures of the skin like epidermis, hair follicles and nail matrices receive their blood supply and hence the nutrition from the cutaneous vasculature. Topically applied nutrients thus play no role in enhancing the nutrition of the skin and its structures and their growth. The skin disorders arising from avitaminoses or malnutrition can genuinely be corrected by nutritional supplements. The other skin structures like stratum corneum, hair and nail consist of dead cells and application of external agents like protein, amino acids and elastin do not help these structures.

2) Micronutrients of the skin

http://www.findarticles.com/cf_0/m0HMW/8_5/91708254/p2/article.jhtml

It reads:

Micronutrients important mediators of skin aging, Cosmetic Surgery Times, Sept, 2002, by Cheryl Guttman

Chicago -- The mechanical pathways of aging can be altered by a variety of micronutrients, so diet and nutritional supplements can play a valuable role in preventing skin aging, said Ronald Hoffman, M.D., at the annual International Symposium on Aging Skin.

3) "sensory agents"

http://www.sensorysolutions.com/science.html

Cosmetic and skin care products present a unique challenge to sensory analysts because their properties are elusive, difficult to describe, and produce extremely subjective reactions. To illustrate, even if the only difference between two moisturizers is the fragrance each contains, many of the other performance characteristics may be rated differently because of the judge's preference for one fragrance over the other

Fragrance preference is often based on an emotional association in an individual's memory. In nearly all instances, a consumer's immediate impression of a skin care product is influenced by its fragrance; the consumer at once recalls familiar objects, products, or situations having a similar fragrance and associates meanings, feelings, and connotations with them. He or she forms a positive or negative opinion regarding the fragrance, which often is transferred to the product itself. This influence can strongly affect the consumer's ultimate acceptance or rejection of the product. The sensory analyst of cosmetic products must minimize biases and providing accurate, actionable information to development chemists